Health Legislation Amendment Regulation (No. 2) 2025

Explanatory notes for SL 2025 No. 151

made under the

Hospital and Health Boards Act 2011
Medicines and Poisons Act 2019
Public Health Act 2005

General Outline

Short title

Health Legislation Amendment Regulation (No. 2) 2025.

Authorising law

Sections 151 and 282 of the *Hospital and Health Boards Act 2011*
Sections 75 and 240 of the *Medicines and Poisons Act 2019*
Sections 64 and 461 of the *Public Health Act 2005*

Policy objectives and the reasons for them

The objective of the *Health Legislation Amendment Regulation (No. 2) 2025* (Amendment Regulation) is to amend the:

- *Public Health Regulation 2018* to remove Japanese encephalitis (JE) and Murray Valley encephalitis (MVE) as pathology request notifiable conditions;
- *Hospital and Health Boards Regulation 2023* to update the reference to the information sharing agreement between Queensland Health and Services Australia, enabling improved identification of women eligible for BreastScreen Queensland's free breast screening service;
- *Medicines and Poisons (Medicines) Regulation 2021* to clarify that the processing fee for an initial application for a substance authority[1] applies only to licences and has not applied to general and prescribing approvals since the commencement of the regulation on 27 September 2021;

[1] A substance authority is a manufacturing licence; wholesale licence; retail licence; pest management licence; prescribing approval; or a general approval.

- *Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021* to clarify that the processing fee for an initial application for a substance authority and the fee for replacing a lost, stolen, or damaged hard copy document applies only to licences. These fees have not applied to general approvals since the commencement of the regulation on 27 September 2021; and
- *Medicines and Poisons (Pest Management Activities) Regulation 2021* to make a minor and consequential amendment to ensure consistency in the language used across the medicines and poisons scheme.

Public Health Regulation

The *Public Health Act 2005* provides a regulatory framework for identifying and managing notifiable conditions that pose a significant risk to public health, either due to their potential for spread, severity or impact on vulnerable populations. The list of notifiable conditions and the circumstances in which they are notifiable (for example, provisional diagnosis, pathology request, positive diagnosis) are set out in schedule 1 of the Public Health Regulation.

JE is a mosquito-borne virus that transmits infection to humans through the bite of a mosquito infected with the JE virus. In severe cases, a person may develop acute encephalitis (inflammation of the brain). However, less than one percent of people infected with JE present with symptoms.

MVE is a disease caused by the MVE virus, spread to humans through the bite of an infected mosquito. Similar to JE, most people with MVE remain well. However, a small proportion of people infected develop encephalitis, which can be fatal, or for those that recover, may result in permanent neurological impacts.

Under schedule 1 of the Public Health Regulation, JE and MVE are prescribed as both pathology request notifiable conditions and pathological diagnosis notifiable conditions. Laboratories are required to notify Queensland Health within 48 hours when they receive a request to test for JE or MVE and immediately notify Queensland Health (see section 32 and schedule 2 of the Public Health Regulation) when pathology indicates a positive case, due to the viruses' potential severity.

Queensland is the only jurisdiction in Australia that prescribes JE and MVE as pathology request notifiable conditions. This exceeds the national minimum reporting requirements set by the Communicable Diseases Network Australia, which only require notification of confirmed and probable cases. JE and MVE are also nationally notifiable diseases under the National Notifiable Diseases List, which only includes notification of new cases.[2]

In Queensland it is standard practice for public health units to only follow-up on pathologically diagnosed cases of JE and MVE (pathological diagnosis notifications), not suspected cases (pathology request notifications). Although some public health units may review pathology request notifications of JE and MVE, they only monitor suspected cases if they are aware the person is in hospital with symptoms of encephalitis.

[2] List of nationally notifiable diseases. Accessed here: www.health.gov.au/topics/communicable-diseases/nationally-notifiable-diseases/list.

Removing the pathology request notification requirement will:

- align Queensland's reporting obligation with national standards and practices;
- reduce unnecessary administrative burden on laboratories and public health units; and
- ensure public health resources are focused on confirmed cases that require intervention.

Importantly, the requirement for immediate notification upon diagnosis remains unchanged, ensuring public health units can respond promptly if a suspected case is confirmed.

Hospital and Health Boards Regulation

The BreastScreen Queensland (BSQ) program is the state program of BreastScreen Australia, providing free breast screening to women aged 40 and over.

For women, the risk of breast cancer increases greatly after the age of 50. As about 80 per cent of breast cancers occur in women over 50, breast screening is most effective for women aged 50 to 74. If a woman has not had a breast screen with BSQ by age 50, the BSQ program sends an invitation to the woman to start screening.

In 2019, Queensland Health entered into an agreement with the Commonwealth Department of Human Services, now known as Services Australia (2019 Agreement). The 2019 Agreement allows Queensland Health to access Services Australia's Medicare enrolment information for the purposes of identifying women in the target age group and inviting them to participate in the BSQ program. Under the 2019 Agreement, Queensland Health is permitted to access basic demographic information including name, date of birth and postal and residential addresses. However, telephone numbers and email addresses are excluded, limiting outreach to postal invitations only.

In September 2025, Queensland Health entered into a new agreement with Services Australia (2025 Agreement). The 2025 Agreement allows for the sharing of additional contact information for eligible women, such as telephone numbers and email addresses. This enhancement enables BSQ to contact eligible women via SMS, telephone and email, which recent trials have demonstrated are a more effective means of communication for increasing participation in the BSQ program.

The Amendment Regulation amends the Hospital and Health Boards Regulation to give effect to the 2025 Agreement and ensures:

- the regulation reflects the current legal basis for data sharing;
- Queensland Health can fully utilise modern communication channels to increase screening uptake; and
- the BSQ Program remains responsive to evolving public health needs and technological capabilities.

Medicines and Poisons scheme

The *Medicines and Poisons Act 2019* establishes a regulatory framework to ensure particular substances are manufactured, sold, used and disposed of in a safe, effective and appropriate manner. The Medicines and Poisons Act also provides a mechanism for managing health risks associated with the use of these substances.

Under section 240(2)(j) of the Medicines and Poisons Act, regulations can prescribe fees for applications and other matters under that Act.

Fees for applications for substance authorities are prescribed in:

- Schedule 19 of the *Medicines and Poisons (Medicines) Regulation 2021* (Medicines Regulation);
- Schedule 6 of the *Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021* (Poisons Regulation); and
- Schedule 2 of the *Medicines and Poisons (Pest Management Activities) Regulation 2021* (Pest Management Regulation).

A substance authority refers to a licence or approval that authorises a person to carry out a regulated activity with a regulated substance. These include manufacturing, wholesale, retail and pest management licences, as well as prescribing and general approvals.

The fees outlined in the Medicines Regulation and Poisons Regulation are for licences to engage in wholesale, retail or manufacturing. However, there is also a general processing fee of 140.50 fee units ($153.98), which could be interpreted as applying to applications for substance authorities other than licences, specifically:

- prescribing approvals (for example, approvals for medical practitioners prescribing approved opioids for patients under the Queensland opioid treatment program); and
- general approvals (for example, approvals that enable emergency first aid, or research or analysis using hazardous poisons).

Additionally, the Poisons Regulation prescribes a fee of 55.50 fee units ($60.82) to replace a lost, stolen, or damaged hard copy document evidencing a substance authority. Again, this prescribed fee could be interpreted as applying to all replacement documents, including those that evidence substance authorities other than licences.

The objective of the amendments is to clarify that processing fees are only payable for licences. The effect of this amendment is that no processing fees are payable for:

- general approvals for dealing with hazardous poisons; and
- general or prescribing approvals for dealing with a medicine.

The amendments apply retrospectively to confirm that this interpretation has been in effect since the commencement of the medicines and poisons regulatory scheme on 27 September 2021. No fees have ever been sought or paid for these types of approvals.

Additionally, the amendments clarify in the Poisons Regulation that holders of general approvals are not required to pay a fee for replacement hard copy documents evidencing their approvals. This change also applies retrospectively from 27 September 2021. No fees have ever been sought or paid for these replacement copies.

The Amendment Regulation also makes a minor, consequential amendment to the Pest Management Regulation to ensure the language used regarding a processing fee for an initial application is consistent across the three regulations.

By making these changes, the regulations will accurately reflect the applied fee structure and provide certainty regarding the past and future payment of these fees.

Achievement of policy objectives

The Amendment Regulation commences on notification.

Public Health Regulation

By amending schedule 1 of the Public Health Regulation to no longer make JE and MVE pathology request notifiable conditions, the Amendment Regulation streamlines laboratory notification processes and optimises resources in public health units by only prompting a follow up if a laboratory diagnoses a case of JE or MVE. The Amendment Regulation will also align Queensland's JE and MVE notification requirements with other Australian jurisdictions, and with national best-practice guidelines.

JE and MVE will remain as pathological diagnosis notifiable conditions that are immediately notifiable on pathological diagnosis, ensuring Queensland Health continues to receive timely and essential data to monitor and understand the disease epidemiology and respond effectively to diagnosed cases and potential outbreaks.

Hospital and Health Boards Regulation

To give effect to the 2025 Agreement, the Amendment Regulation amends schedule 8, part 1, section 10 of the Hospital and Health Boards Regulation by replacing the reference to the 2019 Agreement with the 2025 Agreement. This change facilitates continued data exchange between Queensland Health and the Commonwealth for identifying women eligible for breast screening services, supporting the BSQ program.

Modernising the method by which eligible women are contacted to participate in the BSQ program is expected to improve screening participation rates. This reform represents a positive step forward in promoting women's health and supports the strategic goals of BSQ.[3]

Medicines and Poisons scheme

The Amendment Regulation clarifies that processing fees are only payable for certain types of substance authority applications under the Medicines and Poisons framework. Specifically, it amends:

- Schedule 19, item 9 of the Medicines Regulation; and
- Schedule 6, item 7 of the Poisons Regulation.

These amendments clarify that the processing fee for an initial application is only required for:

- a manufacturing licence or wholesale licence for an S2, S3, S4 or S8 medicine;
- an S2 retail licence;
- a manufacturing licence or wholesale licence for a hazardous poison; and
- an S7 retail licence.

[3] BreastScreen Queensland Strategic Plan 2025-2032. Accessed here: www.health.qld.gov.au/__data/assets/pdf_file/0027/1403856/breastscreen-queensland-strategic-plan-2025-2032.pdf.

The Amendment Regulation also clarifies that under schedule 6, item 8 of the Poisons Regulation, a fee is only required for replacing a lost, stolen or damaged hard copy document evidencing a manufacturing licence or wholesale licence for a regulated poison or for an S7 retail licence.

These amendments are intended to remove any ambiguity in the Medicines Regulation and Poisons Regulation and confirm the interpretation that has always been applied in practice. No fees are, or have ever been, sought for substance authorities, other than for the licence types mentioned above. To ensure consistency with this longstanding approach, transitional provisions are included to apply the amendments retrospectively from 27 September 2021, the commencement date of the medicines and poisons scheme. This retrospective application resolves any uncertainty about relevant applications submitted without a fee since that date.

The amendment to schedule 2, item 4 of the Pest Management Regulation is minor and consequential and intended to maintain consistency in language across the regulations. It does not substantively alter the effect of the provision.

Consistency with policy objectives of authorising law

The Amendment Regulation is consistent with the policy objectives of the authorising Act.

Inconsistency with policy objectives of other legislation

No inconsistencies with the policy objectives of other legislation have been identified.

Alternative ways of achieving policy objectives

No alternative ways of achieving the policy objectives have been identified. The Amendment Regulation is the only effective means of achieving the policy objectives.

Benefits and costs of implementation

There are no significant financial or resource implications associated with the proposed amendments. Any financial impacts for government will be managed within existing budget allocations.

Consistency with fundamental legislative principles

The Amendment Regulation is generally consistent with fundamental legislative principles in section 4 of the *Legislative Standards Act 1992*. However, it may impact on the following fundamental principles.

Whether the legislation has sufficient regard to the rights and liberties of individuals (*Legislative Standards Act 1992,* S 4(2)(a))

Right to Privacy

The right to privacy, the disclosure of private or confidential information, and privacy and confidentiality issues have generally been identified by the former Scrutiny of Legislation Committee as relevant when considering whether legislation has sufficient regard to an individual's rights and liberties.

The Amendment Regulation amends the Hospital and Health Boards Regulation by replacing the reference to the 2019 Agreement with the 2025 Agreement. The 2025 Agreement enables the sharing of additional contact information, such as telephone numbers and email addresses, for women eligible for BSQ's free breast screening service.

This additional contact information enables Queensland Health to contact eligible women via SMS, telephone and email, which are methods shown to be more effective in increasing participation in the BSQ program and improving health outcomes for women.

While the 2025 Agreement permits the disclosure of patient information, privacy concerns are mitigated through strict compliance with relevant privacy legislation, including the *Privacy Act 1988* (Cth), *Information Privacy Act 2009* and Information Privacy Principles. Additionally, section 151(2) of the *Hospital and Health Boards Act 2011* provides additional safeguards by ensuring that confidential information is not disclosed to any third party unless specifically authorised under the agreement.

The Amendment Regulation therefore maintains appropriate regard to the right to privacy by ensuring that any disclosure of personal information is lawful, limited in scope, and subject to robust safeguards.

Legislation should not adversely affect rights and liberties, or impose obligations, retrospectively (*Legislative Standards Act 1992,* S 4(3)(g))

Section 4(3)(g) of the Legislative Standards Act provides that legislation should have sufficient regard to the rights and liberties of individuals, including by not adversely affecting those rights or imposing obligations retrospectively.

The Amendment Regulation introduces transitional provisions to retrospectively clarify that:

- no processing fee is payable for initial applications for general and prescribing approvals under the Medicines Regulation and the Poisons Regulation; and
- no replacement fee is payable for lost, stolen or damaged hard copy documents evidencing a general approval under the Poisons Regulation.

These amendments apply retrospectively from 27 September 2021, the commencement date of the medicines and poisons regulatory scheme. This ensures the regulations clearly reflect the interpretation that has consistently been applied in practice. Fees have never been charged or collected for the processing of prescribing and general approvals.

Section 34 of the *Statutory Instruments Act 1992* provides that a provision of a statutory instrument may have retrospective effect if it is beneficial in nature, that is, it does not decrease a person's rights or impose new liabilities. The retrospective application of these amendments is considered beneficial because it removes a financial obligation rather than imposing one. It does not diminish any individual's rights or impose new liabilities.

This clarification ensures that for substance authorities other than licences, all applications and replacement requests submitted without a fee since 27 September 2021 are not affected. It provides certainty for authority holders and supports the integrity of the regulatory framework.

In 2025, Queensland Health has processed, on average, over 1,500 initial applications each month for general and prescribing approvals. The retrospective application of these amendments is necessary to avoid administrative disruption, maintain regulatory compliance, and uphold public confidence in the operation of the medicines and poisons scheme.

Consultation

In September 2025, a consultation paper on the proposed amendments, excluding the processing fee amendments, was published on the Queensland Health website and disseminated to stakeholders across medical, nursing, pharmacy, infectious disease and cancer peak bodies, Aboriginal and Torres Strait Islander health organisations, custodial groups and Queensland Health, including Queensland Ambulance and the 16 Hospital and Health Services.

All stakeholders were supportive of the amendments, as detailed below.

Public Health Regulation

All stakeholders who provided feedback on the JE and MVE amendments supported the proposal, including Royal Australian College of General Practitioners (RACGP) and Queensland Nurses and Midwives' Union. It was considered the amendments are an appropriate response to reflect contemporary public health practice.

Hospital and Health Boards Regulation

Stakeholders who provided feedback on the amendments to update reference to the 2025 Agreement for information sharing supported the proposal, including RACGP, the Pharmaceutical Society of Australia (Queensland Branch) and Brisbane South Public Health Network (Brisbane South PHN).

Brisbane South PHN acknowledged the potential for these amendments to improve health outcomes for people living with, or at risk of, breast cancer.

Medicines and Poisons scheme

No consultation was undertaken on the proposed amendments to the Medicines Regulation, Poisons Regulation and Pest Management Regulation. The amendments are considered beneficial and unlikely to attract stakeholder concern given they do not impose new obligations or reduce existing rights.